



# Declaration of Conformity


## Self-Certify

This European Declaration of Conformity is issued under the sole responsibility of the manufacturer.

MANUFACTURER		
Name of Company	Address	SRN
TyTek Medical Inc.	8904 Beckett Rd West Chester, OH 45069, US	US-MF-000032794

AUTHORIZED REPRESENTATIVE			
Name of Company	Address	SRN	Telephone/fax/email
Emergo Europe	Westervoortsedijk 60 6827 AT Arnhem The Netherlands	NL-AR-000000116	+31.70.345.8570 - phone EmergoEurope@ul.com

IMPORTER	
Name of Company	Address
MedEnvoy Global B.V.	WTC The Hauge Prinses Margrietplantsoen 33 Suite 123 2595 AM The Hauge, The Netherlands

PRODUCT IDENTIFICATION		
Product Name	Product Code / Catalog Number	Basic UDI-DI
Piranha Trauma Shears	TM -705, TM 707	0855204008_TSHEARSEE
Intended Purpose	Photo	
Remove Clothing and cut gauze in trauma care		

RISK CLASS FOR MEDICAL DEVICES	
Device Classification	Common Specifications
Class 1, Non-sterile Rule 1	NA

TyTek Medical declares that the above-mentioned products meet the provision of the following EU legislation:

- Medical Devices Regulation (EU) 2017/745

**COMPANY REPRESENTATIVE:** Mark Sweatman

**TITLE:** Management Representative      **SIGNATURE:**

**PLACE:** West Chester, OH US      **DATE:** See Signature